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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,307	10/16/2001	Ganapati R. Mauze	10003714	7843

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EXAMINER
FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,307	MAUZE ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *9-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 14-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

1. In the response, Applicant indicates that the references were submitted. Not only are the references not found in the file, but there is no copy of the 1449 or of an IDS submission after the mailing date of the previous non final action in the electronic file. Therefore, the references still cannot be considered.

Claim Interpretation

The current claims are drawn to "cartridges" which comprise one of a variety of systems, without any structural elements present in the claim. A careful review of the specification finds that the specification itself lacks any structural limitations on the claimed "cartridges". However, because the claim does not use the "means plus function" format, the claim will not be deemed indefinite as per *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376, 58 USPQ2d 1801, 1806 (Fed. Cir. 2001), but rather will be interpreted broadly to include any component which can achieve the claimed function whatsoever.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-8 and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (U.S. Patent 5,856,174).

Lipshutz teaches a "cartridge" (see figure 3 and column 2, lines 15-43) and an analytical instrument (see figure 3) which comprises a fluid transport system (column 2, line 23), a hybridization reaction chamber (see column 2, lines 26-28), or an amplification chamber used for PCR amplification (see column 2, lines 48-53 and column 6, lines 28-67). Lipshutz teaches that the "cartridge" may be connected to a sensing "cartridge" either directly or indirectly (see column 11, lines 48-52).

With regard to claim 2, Lipshutz teaches the use of a fluid interface such as capillary electrophoresis for detection (see column 12) as well as by a mechanical/electrical interface into a reader device (column 13, lines 25-35).

With regard to claims 3 and 7, Lipshutz teaches fluid transport to remove unwanted materials (see column 6, lines 3-27, for example).

With regard to claims 4, 15, Lipshutz teaches DNA testing (see column 6, lines 28-67).

With regard to claims 5, 18, Lipshutz teaches thermocycling to perform PCR (see column 6, lines 28-67).

With regard to claim 6, Lipshutz teaches fluid systems which transport fluid to some chambers thereby increasing their volume (see column 2, lines 15-43).

With regard to claim 8, Lipshutz teaches fluid transport of DNA to a hybridization array, so the fluid is not mixed with the bound oligonucleotide probes (see column 2, lines 15-43).

With regard to claims 16 and 17, Lipshutz teaches cell lysis and DNA extraction (see column 5, lines 15-20, where Lipshutz discusses extraction of nucleic acids from whole cells).

With regard to claims 19 and 20, Lipshutz teaches a removable cartridge (see column 26, line 43 to column 28, line 24), where the cartridge is in fluid contact with the base (see column 18, lines 43-49, for example).

4. Claims 1-8, 14-17, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakata et al (U.S. Patent 5,296,378).

With regard to Sakata, the flow cytometer column is interpreted as the "companion cartridge" while the laser detection and photomultiplier tube are interpreted as the "sensing cartridge".

Sakata teaches a "cartridge" (see figure 1 and column 12, line 20, where a Sakata teaches a flow cell 14 which is a "companion cartridge" that permits fluid flow) which is directly connected mechanically and electrically to a "sensing cartridge" (see figure 1 and column 12, lines 21-39, where the optics detect the sample using a photomultiplier tube). Sakata also teaches an "analytical instrument comprising the cartridges (see figure 1).

With regard to claims 2, 3 and 7, Sakata teaches a flow cell which permits fluid transport between regions (see figure 1 and column 12, lines 1-39).

With regard to claims 4, 6, 8, 15, Sakata teaches flowing a carrier fluid which permits a hematology assay to be performed and which adds liquid to the flow cell (see 11, lines 38-50, column 12, lines 1-39).

With regard to claim 5, Sakata teaches "incubation" of the sample as it flows through the flow cell 14 (see column 12, lines 1-39).

With regard to claim 16, Sakata teaches lysis of a cell (see column 12, lines 55-62, where erythrocytes are selectively lysed).

With regard to claim 17, the lysis of the cells inherently causes DNA to be isolated from the mitochondria (see column 12, lines 55-62).

With regard to claims 18 and 19, the flow cell can be removed from the flow cytometer, inherently and the flow cytometer has a carrier fluid system (see figure 1).

5. Claims 1-8, 14, 15 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Andresen et al (U.S. Patent 6,126,804).

Andresen teaches a "cartridge" (see figures 1 and 2) and an analytical instrument (see figures 1 and 2) which comprises a PCR reaction wells linked to capillary electrophoresis columns (see columns 3 and 4). Andresen teaches attachment of the column to a sensor which detects the amplified DNA (see column 4, lines 1-8).

With regard to claim 2, Andresen teaches the use of a fluid interface such as capillary electrophoresis for detection (see column 4) as well as by a mechanical/electrical interface into a reader device (see figure 5 and column 5, lines 17-25).

With regard to claims 3 and 7, Andresen teaches a flow cell which permits fluid transport between regions (see figures 1 and 2).

With regard to claims 4, 15, Andresen teaches DNA testing (see column 5, lines 1-30).

With regard to claims 5, 18, Andresen teaches thermocycling to perform PCR (see column 3, lines 55-65).

With regard to claim 6, Andresen teaches fluid systems which transport fluid to some chambers thereby increasing their volume (see figure 1).

With regard to claim 8, Andresen teaches fluid transport of DNA in a capillary electrophoresis column, so the fluid is a "carrier" for the amplified product (see column 5, lines 1-40).

With regard to claims 19 and 20, Andresen teaches a removable cartridge (see figure 1), where the cartridge is in mechanical contact with the detection device (see figures 1, 2 and 5).

Response to Arguments

6. Applicant's arguments filed December 23, 2003 have been fully considered but they are not persuasive.

7. Applicant argues that the references do not teach cartridges. However, the cited support for the term, paragraph 27, lines 1-6, are not limiting and impose absolutely no structural requirements upon the claims. The cited portion states "The companion cartridge can be designed to fit one or more instruments and interact with one or more types of sensing cartridges. The design features permit changing and switching the sensing cartridge, without having to replace the companion cartridge. This is because the companion cadridge is removable, and does not need to be attached to the sensor cartridge for operation with the instrument." This is not a limitation of the claim, or even of the specification, but rather a recitation of a preferred possible embodiment. The

cartridge "CAN BE DESIGNED to fit one or more instruments." First, there is no requirement that it is so designed. Second, even if there were such a requirement, how does this structurally distinguish the cartridge from anything else whatsoever. This implies no structure at all. Therefore, the term "cartridge" will continue to be read broadly as any structure whatsoever. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant then argues that Lipshutz does not teach a sensing cartridge. This is not correct. As noted in the rejection, Lipshutz teaches detection at column 11, by devices including a confocal microscope. Such a device would detect changes in fluorescence, which are related to changes in the chemical structure of the molecules, meeting the "sensing cartridge" requirement.

Similarly, Sakata teaches a device which would detect changes in fluorescence, also meeting the "sensing cartridge" requirement as discussed in the rejection.

8. In both of these cases, Applicant refers to paragraph 6 of the specification which discusses detection of chemical analysis as lacking in the references. First, claim 4 expressly recognizes DNA testing as a "chemical reaction" and the devices of Lipshutz and Sakata would measure a number of chemical parameters in DNA analysis including amplification efficiency, polymerase activity, or hybridization affinity, for example. Second, the term is not defined in the claim and any limitations Applicant is trying to import from the specification, (none of which are evident), are currently in the claim. Although the claims are interpreted in light of the specification, limitations from the

specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Andresen does not teach a "removable cartridge". This word does not appear in the claims and therefore this argument is not relevant to the claims at issue. Similar to above, Andresen teaches forms of chemical analysis which clearly meet the intentions of the specification and claim 4 and therefore fall within the scope of the claims.

For these reasons, the rejections are maintained.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
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Art Unit 1634